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ABSTRACT

The ethical codes for experimentation adopted by most professional organizations include references to the requirement that subjects be given at least minimal information about their involvement in research, but are generally silent on the necessity of ascertaining whether or not subjects sufficiently comprehend the information given. For moral, legal, and pragmatic reasons the issue of comprehension is particularly important when the potential subjects are children. A survey of ethical codes reveals that most of them sidestep the issue by relying on parental consent alone. When in some instances they attempt to cope with the problem, the usual solution to determining whether or not children are able to understand enough to consent is to designate the common law "age of discretion" of seven years as the standard. This paper proposes an alternative standard, the child's cognitive competence. It specifies the cognitive abilities of children necessary to comprehend the information which codes require researchers to give subjects. Using a Piagetian schema, the paper analyzes the nature of these cognitive abilities and how they develop. Minimal procedures for insuring that informed consent has been obtained from children are outlined. (Author/RH)

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Informed Consent in Research with Children:

A Piagetian Approach

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Since the formulation of the Nuremberg Code in 1949, one of the generally accepted requirements for the ethical conduct of research with human subjects has been the voluntary, informed consent of the participants. The ethical codes of many professional organizations include references to the requirements that subjects be at least minimally informed about their involvement in research and that their consent to participation be freely given. What the authors of these codes mean by "informed" is, however, by no means clear.

The amount and type of information necessary to ensure informed consent varies from code to code (see Figure 1, pp. 26-29). Despite this variation, the definition set out in the Nuremberg Code (1949) seems to underlie most of the criteria agreed on by the various professional organizations.

> The person involved should have legal capacity to give consent; . . . and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. . . . This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected and the effects upon his health or person which may possibly come from his participation in the experiment (p. 181).

Important questions remain, however, about what "sufficient comprehension" means and how this sufficiency is ascertained.

The issue of comprehension is particularly critical when the potential subjects are children and other vulnerable individuals. The current trend toward recognition of the legal and human rights of children makes this issue a particularly important one. Morally, the researcher may feel that the child, as an autonomous individual, has a right to understand and make decisions about being exposed to procedures which will affect her. Pragmatically, the child's informed consent may assure her cooperation in all phases of the study. Legally, a researcher may be liable to the child for the consequences of a study consented to only by the parents.

Many ethical codes do attempt to deal with the issue of consent by children, but they are usually less specific on this point than on others. There is almost universal agreement that the consent of a parent or guardian is necessary when the subject is not legally competent to consent (see Figure 1, pp. 26-29). The obligation to obtain the consent of the children themselves is less clear. Most codes recommend informing children in terms appropriate to their comprehension (SRCD), or obtaining the informed consent of children when that is feasible (APA). In fact, however, a recent SRCD survey (Charlesworth & Lougee, 1976) showed that, of those researchers surveyed who studied elementary school age

children, only about 33% obtained consent from the subjects. Even when working with adolescents, only 75% of the researchers obtained the subjects' consent. In contrast, "adults, when studied, were almost always likely to be asked to give their own consent (90%)" (Charlesworth & Lougee, 1976, p. 5). These findings seem to be in conflict with SRCD's ethical guidelines and demonstrate the potential drawbacks of a statement as vague as that of SRCD concerning the consent of children.

Perhaps one deterrent to securing the consent of children to participation in research is the inherent difficulty in determining whether they can formulate the requisite judgment to consent. The authors of the NIH guidelines (1973) acknowledge this difficulty when they say, "clearly, infants have neither the comprehension, nor the independence of judgment essential to consent; older children might or might not have these capabilities" (1973, p. 31742). Because of this element of doubt, they propose the "common law 'age of discretion' of 7 years" (p. 31742) as the age when consent of the child must be obtained.[1]

The advantages of using age as a criterion are almost immediately obvious. Age offers a totally objective standard and is, in most cases, easy to ascertain. On the other hand, the use of

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[1]A recent unpublished paper written for NIH by Ferguson (note 1) on informed consent may have some impact on these standards.

age as a criterion poses problems which tend to outweigh these advantages. A strict age criterion does not take into account differing rates of maturation or levels of intellectual ability, nor does it allow for discrepancies in performance that may exist as of function of environment or background.

For this reason, the standards for informed consent should be based directly on the child's cognitive abilities, fulfilling the intentions of the NIH guidelines, rather than on age. The abilities that are necessary and sufficient for the child to understand the elements of a research study in order to make an intelligent decision about participation must be determined.

Necessary and Sufficient Abilities

Implicit in the notion of informed consent as set forth in the organizational guidelines surveyed is a requirement that the subject have some basic intellectual competence. For example, the subject must be able to understand and use language; must have at least minimal independence; and must be capable of symbolic functioning. Beyond this minimal level of ability, however, the competencies necessary for informed consent are not readily apparent.

One approach to discovering the nature of these competencies is to isolate the concepts which are basic to an understanding of the information required for informed consent. If the child does

not have the ability to use these concepts she is then, almost by definition, unable to give even minimally informed consent. As the child becomes able to deal with these concepts on a more sophisticated level she will gradually become capable of giving fully informed consent.

The codes taken together require that the subject comprehend: that she is to be a subject in a study; the purpose of the study; the nature of the research; the sponsorship of the study; why she was selected to participate; the procedures to be employed; the anticipated duration of the study; possible uses of the data; potential beneficial aftereffects; potential harmful aftereffects; experiences to be expected during the experiment; long- and short-term risks; long- and short-term discomforts; anticipated benefits to the subject; anticipated benefits to others; alternative methods of treatment; her freedom to ask questions; her freedom to withdraw.[2] These types of information were analyzed in terms of the cognitive abilities required for their comprehension. We determined that four concepts were basic to all of them: causality, probability, time, and decentration or social feeling.

We realize that this list may not be exhaustive. We also realize that the child's ability to use such concepts is not

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[2]Levine (note 2) has developed an alternative list of elements which is not identical to ours. It appears in an unpublished paper of which we became aware after this list had been prepared.

sufficient evidence that she will be able to give informed consent. For example, there are certainly other requirements related to the child's social, emotional, and physical state that should be considered. However, we believe that knowledge of the child's level of cognitive development coupled with an analysis of the level of conceptual sophistication required for comprehension of the information will: (a) provide a flexible criterion for determining how much the child should be told; and (b) help in developing specific procedures for gaining informed consent.

Level of Conceptual Development Necessary for Comprehension of Information

Causality

In order to understand the benefits or risks of a study, the purposes of a study, and the basic experimental design, a subject must have some understanding of causality (or cause and effect relationships).

The preoperational child is, in Piagetian terms, precausal. The child interprets reality in terms of final or moral causes, rather than physical causes (e.g., A rod goes into the water because it has to. There are two mountains so people can go on short and long hikes). While there seems to be a need for ultimate explanation (Piaget & Inhelder, 1969, p. 110), there is no

search for noncontradictory physical explanations (Inhelder & Piaget, 1958, p. 22). This is, of course, related to the child's inability to see the reversibility of operations or the conservation of properties of objects.

In the concrete operational stage, the child does perceive causal relationships. However, at this stage the child cannot isolate variables (Inhelder & Piaget, 1958, p. 70) or comprehend fully interactive causation (Inhelder & Piaget, 1958, pp. 111-116). For example, when a combination of two colorless liquids yields a colored liquid, the child in the concrete operational stage believes this is caused by a color pellet hidden in one of the liquids (Inhelder & Piaget, 1958, p. 116). These and similar limitations are gradually removed in the formal operational stage so that, for the first time, the child (adolescent) can understand interrelated causal factors and the experimental method.

With regard to informed consent, it appears that a child in the preoperational stage will have difficulty in understanding the idea of the effect of a future action. At best, the child will be able to see it in temporally sequential or final causal terms. The danger in this is that the child may interpret harm to herself in terms of moral rather than physical causality, understand a discussion of risk to be a threat of punishment. The child in the concrete operational stage will be able to understand the relation-

ship between the experiment and its results, but only insofar as the effect is uni-causal. Only the child in the formal operational stage will be able to fully understand both the consequences of the experiment and the experimental method itself.

Probability

For a subject to comprehend possible benefits, risk to the participants, and even anticipated use of data, she must have some understanding of probability. Each of these requires the ability to distinguish between probability and necessity, on the one hand, and mere possibility on the other.

Piaget defines probability as the relationship between positive confirming cases, or favorable cases, and possible cases. This idea, which seems like a simple one, is, however, late in developing. "At the preoperational level the subjects' attitudes toward chance are paradoxical. . . . They expect that under similar conditions given phenomena will be repeated, either identically or in terms of a definite progression, etc. When they do realize that there are small fluctuations they . . . conclude that [the effect] is completely arbitrary" (Inhelder & Piaget, 1958, p. 225). The child does not distinguish between the possible and the necessary. Since she has not developed operations, nothing is totally predictable and nothing is total unforeseen. Thus, at this stage, an

explanation that something may happen is not functionally different from an explanation that something will happen. Since every result is unpredictable, a fortuitous result is undifferentiated from a systematic one.

With the beginning of the concrete operational stage comes an understanding of possibility. "The child succeeds in seeing through to the possibility of fortuitous combinations, permutations, or arrangements" (Piaget & Inhelder, 1976, p. 214). "Chance is at first conceived only in a negative sense as an obstacle to deductibility" (Piaget and Inhelder, 1969, p. 113). The child understands that the actual outcomes are related to total possible outcomes in a way that is not operationally defined. However, it is only later in this stage that the child begins to account for all the possible outcomes and to predict the occurrence of favorable outcomes in large numbers of cases. In terms of experimentation, the child now understands that a risk is something that may happen, but is not yet capable of understanding the likelihood of it happening. By the end of the concrete operational stage she may be able to understand very simple probabilities, but not those involving combinations of multiple factors (e.g., the results of a coin toss as opposed to the chances of drawing numbers in a particular order and frequency). Most analyses of risk will involve the second, more complex type of determination of probability.

Thus, "It is not until the age of eleven or twelve (formal operations) that the child understands combinatorial probabilities, or such notions as fluctuation, correlation, or even probable compensations with the increase of numbers (Piaget & Inhelder, 1969, p. 144). Ideas like "65 times out of 100" or "depending on the amount of treatment, the patient's physical abilities, and the environmental conditions" which involve comprehending consistency over large numbers of cases or a multiplicative combination of possibilities and probabilities become clear only at this stage of development. Since "thought bearing on the possible is . . . formal thought which . . . [is] hypothetical-deductive, . . . operating on simple possibilities treated as hypotheses" (Piaget & Inhelder, 1975, p. 228), it is at this stage that the child becomes capable of fully understanding the experimental process.

Reflecting on Piaget's analysis it would seem that a pre-operational child will have great difficulty in making any kind of decision on risk, or possible benefit, even if the nature of the harm or benefit itself were totally comprehensible. The concrete operational child will be able to understand the idea of risk as distinct from expected consequence and, to some extent, assess risks explained in terms of small numbers and limited variables. An adolescent in the formal operational stage will be capable of understanding probability of harm or benefit in a

more sophisticated manner and weighing the effects of several factors on that probability. In addition, the adolescent's ability to hypothesize may enable her to understand and evaluate the purpose and procedures of the experiment in scientific terms.

Time

A number of the elements suggested as critical to informed consent are obviously related to a child's ability to deal with concepts of time. The duration of the study, short- or long-term risks and discomforts involved, the aftereffects, and the order of events involved in research procedures all assume, in Piaget's terms, a grasp of temporal order and of durations (additivity and associativity of temporal intervals).

> Time is involved with causality; it is the structure of our own history but only to the extent that we construct or reconstruct it. . . .
>
> To determine time, we must therefore appeal to causal operations, i.e., establish a chain between causes and effects by explaining the latter in terms of the former. Time is inherent in causality (Piaget, 1971, p. 6).

Operational time, as distinct from intuitive time (successions and durations given by direct perception), involves relations of succession and duration based on analogous operations in logic (Piaget, 1971, p. 2). The preoperational child, therefore, has difficulty with notions of temporal order, simultaneity, and duration. Before the age of seven or eight, children are not yet capable of reasoning

about several possibilities at the same time and they lack the power of operational reversibility which mastery of the concept of time presupposes (Piaget, 1971, p. 6). For example, seriating two events over time requires that the child establish not only that one event precedes another, but that the second event succeeds the first. Rational time is a system of reversible operations. It is only the empirical contents of time, i.e., the external or psychological events, that are irreversible (Piaget, 1971, p. 273).

Preoperational children's intuitive conception of time leads to a distortion--once they adopt any sort of sequence they have difficulty in changing their minds. Time for the child in Piaget's preoperational stage is "simply the order of succession and the colligation [fitting of parts into meaningful wholes] of duration of a single series of linear events; irrespective of its own velocity or its interactions with other series with different velocities" (Piaget, 1971, p. 281). Time is localized in that it varies from one motion to the next and is confused with the spatial order. The preoperational child's intuitive grasp of time is tied to spatialization. The concrete operational stage marks the start of decentration and the emergence of "articulated intuitions" (Piaget, 1971, p. 284) subject to relatively constant regulations. Children in this stage are still limited by an

inability to relate succession and duration, but by the age of eight or nine the child learns to base successions on durations, and vice versa, and to group durations.

On the basis of more current descriptions of the stage of formal operational thought (Piaget & Inhelder, 1976), the abilities required to deal with all aspects of time could only emerge during early adolescence. The adolescent becomes able to see many possibilities, to reason about them and to grasp causality, for, as Piaget suggests, the child's conception of time is "constructed." It depends on constituent logical operations, and not until the formal operational stage of development is reached will the child (adolescent) master all the intricacies of thought that would permit full understanding of time.

It follows from Piaget's analysis that a child prior to about the age of eight or nine will be essentially unable to comprehend in any meaningful way factors such as aftereffects, short- and long-term risks, duration of a study, or the temporal order in which events will take place in a research study. Her understanding of notions such as "before" and "after" and the difference between them is extremely limited in that it is tied to spatial distances and perceptual data. The concrete operational child will be able to better grasp concepts of "past," "present," and "future," and their interrelatedness (Maier, 1969, p. 141), but it is not

until the formal operational stage of development is reached that a potential subject will have attained the ability to fully evaluate risks, aftereffects, and duration of a study.

Decentering and Social Feeling

The comprehension of such factors as anticipated benefits to others, use of data as bearing on the interests of groups with which he is identified, and even, sponsorship or purpose of the study depends in part on the subject's "decentering and egocentrism" and "social feelings."

Egocentrism is the inability to differentiate between the points of view of self and others. Decentering is a continuous psychological process which acts in opposition to egocentrism, beginning in the sensori-motor period and continuing through the late formal operational stage. In the sensori-motor stage, egocentrism is evident in the infant's failure to separate her own actions from external events. Later, the preoperational child, who has decentered sufficiently to recognize the external field, is still unable to see differences in representation between self and other.

> When the child reaches the stage of concrete operations . . . he acquires skill in interindividual relations in a cooperative framework. Furthermore, the acquisition of social cooperation and the structuring of cognitive operations can be seen as two aspects of the same developmental process (Inhelder & Piaget, 1958, p. 343).

Thus, it is not until the concrete operational stage that the child can engage in social cooperation or interaction. It is in the formal operational stage that this social cooperation evolves into an identification of the adolescent's interests with those of the wider group. The adolescent experiences a "relative failure to distinguish between his own point of view . . . and the point of view of the group which he hopes to reform" (Inhelder & Piaget, 1958, p. 343). This inability persists until the decentering of adulthood.

Piaget explains that the dialectic between egocentrism and decentering is complemented by affective changes including the gradual development of social feelings or feelings about ideals.

> The notions of humanity, social justice (in contrast to interindividual justice which is deeply experienced at the concrete level), freedom of conscience, civic or intellectual courage, and so forth, like the idea of nationality are ideals which profoundly influence the adolescent's affective life; but with the child's mentality, except for certain individual glimpses, they can neither be understood nor felt (Inhelder & Piaget, 1958, pp. 348-349).

Based on this analysis it would seem that an explanation given to subjects concerning the social consequences which will affect groups other than their immediate family or social network will be meaningless prior to the formal operational stage. For an adolescent in the formal operational stage, however, such information will be not only comprehensible but extremely important,

perhaps more important even than it would be to an adult (because of the formal operational egocentrism referred to above). Consequences to family, friends, etc. can be understood by the child in the concrete operational stage and should be explained to her.

This analysis suggests that issues like long-range purposes of the study, sponsorship of the study, use of data, risks, or benefits to society, etc. should be explained to the adolescent. Some of these (benefit to others, use of data, etc.) might also be explained to the concrete operational child insofar as they relate to others with whom she has a relationship.

Toward More Explicit Procedures for Securing Informed Consent

With these threshold competencies in mind, we can begin to structure procedures for securing informed consent which will: (a) take into account the varying abilities of children; and (b) allow the researcher to provide subjects with information in a comprehensible form. Evidence should be presented to an ethics committee, or kept on file, that the following steps have been followed.

First, an analysis similar to that outlined above has been carried out. The information required to ensure informed consent, as prescribed either by official guidelines or by the investigator's own standards, must have been specified and the underlying concepts

which may become meaningful in the context of the particular study, isolated. In this context, other factors should have been considered. To what extent are the concepts too abstract for a child of a certain age to comprehend? Can the information be simplified or concretized to correspond with the child's conceptual structure? Are there reasons why the child's lack of ability to comprehend might make disclosure of certain types of information damaging?

Second, each individual child's cognitive level has been assessed. Her level may vary in terms of the particular ability or concept to be evaluated (e.g., her concept of time may be more advanced than her notion of probability), so the optimal instrument would be one which assessed the child's cognitive abilities in specific areas. Until an adequate instrument is available, some of Piaget's own research procedures might be employed as indicators of cognitive level. Information obtained in this way about potential subjects might well be useful in the design of the actual study, particularly in cases where the subject is required to perform some cognitive operation as part of the study.

Third, all relevant information has been communicated to the subject in comprehensible form. Grounds for believing that the child has actually comprehended should be included in this evidence. If some relevant information has not been communicated, or has been simplified, this fact should be indicated along with a cognitive justification for such omission or simplification.

Implications and Conclusions

The procedures we have sketched are somewhat involved and complex. However, the difficulties of implementing them must be placed in perspective. They are designed to protect children who are either physically, socially, or psychologically placed at risk (NIH, 1973). The burden they impose on the investigator is far more acceptable than the personal guilt that might be experienced or the legal penalties which might result from carrying out such studies without obtaining informed consent (Children v. parents, 1976). In addition, it must be recognized that researchers often voluntarily implement very intricate procedures in order to ensure that subjects fully comprehend what they must do to respond appropriately during a study. This is done quite systematically to ensure the integrity and validity of the data collected. Surely the scientist's obligations to his human subjects are as great as those to science.

Other problems and questions still remain. The first has to do with the preoperational child. To such children relevant information in its original form will often be incomprehensible and adequate simplification may be impossible. Because of this the researcher has a special responsibility to fully inform the parent or those acting *in loco parentis* and to refrain from carrying out studies in which competent subjects would frequently be unwilling to

participate.

At the other end of the spectrum, the adolescent in the formal operational stage may have, in effect, the cognitive capabilities of an adult. Under these circumstances, the requirement that parental consent be obtained may be not only unnecessary, but even an infringement on the adolescent's right to self-determination. Of course, a legal or social decision to provide additional protections and to secure the rights of parents is defensible. If so, it should be recognized as a social choice, rather than a psychological necessity.

The proposal outlined above does not take into account social-emotional variables such as the fear or anxiety of the child. Procedures have been suggested for dealing with these problems (Catching up, 1976). Such procedures should be used to supplement methods for coping with cognitive obstacles to obtaining informed consent. They are not enough alone.

Finally, attention must be paid to the developmental capacity of the child to give autonomous, voluntary consent. Informed consent not only involves the subject's comprehension of adequate information, but also the subject's autonomy to choose, without duress, whether or not to participate in a study (NIH, 1973). Procedures must be developed which effectively deal with the inherent difficulties of obtaining free consent from children.

These procedures might also be grounded in cognitive theory. The moral developmental theories of Piaget (1965) and Kohlberg (1969) seem particularly suited to the task.

In each of the stages postulated in these theories there would be limits on the child's ability to give free consent. For example, in Kohlberg's view the child's movement through the stages is marked by a change from reliance on physical consequences for determination of "right" or "wrong," to almost complete independence from external criteria. Similarly, Piaget's work on moral development suggests a movement from ritual obedience by the child, to an ability to question authority and established norms. Thus, in each of the stages postulated in these theories there would be limits on the child's ability to give free consent. The changing nature of the limits suggests that different procedures might be used at different levels of moral development to maximize the child's freedom either to give or withhold consent. For example, the optimal time for obtaining parental consent might vary with the developmental level of the child. The knowledge that a parent has already given consent might have a coercive effect on a child at the beginning of the concrete operational stage, but be irrelevant to adolescents capable of formal operational thought.

Much work remains to be done in developing, implementing, and evaluating specific procedures for securing informed, voluntary

consent. This paper simply sketches the contours of the problem and suggests some possible approaches. A concerted effort must now be undertaken to flesh out this proposal so as to ensure that the rights of all--child, parent, and researcher--will be protected.

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Figure 1. Informed Consent Provisions of Selected Organizations

Organization and Year	Required Information to Give When Securing Consent	Special Provisions for Securing Consent from Children
Nuremberg Tribunal, 1949 (Nuremberg Code)	nature, duration, and purpose of the experiment method and means by which it is to be conducted all inconveniences and hazards reasonably to be expected effects on his health or person which may come from the experiment	child must have legal capacity to give consent
World Medical Assoc., 1964 (Helsinki Declaration)	full explanation of clinical research nature, purpose, and risk of non-therapeutic clinical research	consent from legal guardian of child
National Institutes of Health, 1973	nature and purpose of the research nature and purpose of the procedure identification of procedures which are experimental possible attendant short- or long-term risks and discomforts anticipated benefits to himself and/or others any alternative methods of treatment expected duration of the study his or her freedom to ask any questions and to withdraw at any time should [he] wish to do so	consent of both parents of child consent of the child subject over the age of seven right of any child to refuse to participate

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Figure 1. (continued)

Organization and Year	Required Information to Give When Securing Consent	Special Provisions for Securing Consent from Children
American Medical Assoc., 1966	Declaration of Helsinki adhered to clinical investigation primarily for treatment use of an investigational drug or experimental procedure nature of the drug or procedure to be used risks to be expected possible therapeutic benefits alternative drugs or procedures that may be available clinical investigation primarily for accumulation of scientific knowledge use of an investigational drug or procedure nature of procedure to be used and risks to be expected	consent of legally authorized representative of child
American Psychological Assoc., 1973	purpose and sponsorship of study why he was selected to participate procedures to be employed experiences to be expected potentially beneficial or harmful aftereffects	consent of legal guardian of child permission from the child when capable of making responsible judgment

(continued on next page)

Figure 1. (continued)

Organization and Year	Required Information to Give When Securing Consent	Special Provisions for Securing Consent from Children
	possible uses to which the data or conclusions of the study may be put, as these bear upon the participant's interests and values or upon those groups or institutions with which he is identified	
American Psychological Assoc., 1968 (Div. of Developmental Psychology)	accurate information on the profession and institutional affiliation of the investigator purpose and operations of the research	consent of parents of child or those *in loco parentis* is prerequisite to obtaining consent of child child has right to refuse to participate
Society for Research in Child Development, 1973	all features of the research that may affect willingness to participate answer child's questions in terms appropriate to child's comprehension profession and institutional affiliation of investigator (for consent of parents or those *in loco parentis*) reasons for concealment or deception (secured after study, if appropriate)	consent of parents of child or those *in loco parentis* right of child to choose to participate, or not

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Figure 1. (continued)

Organization and Year	Required Information to Give When Securing Consent	Special Provisions for Securing Consent from Children
	possibility that others may gain access to participant's identity (if appropriate) plans for protecting confidentiality	
American Sociological Assoc., 1971	none	none
American Anthropological Assoc., 1973	aims of the investigation capacities of data-gathering devices anticipated consequences of the research	none
American Personnel and Guidance Assoc., 1974 (rev.)	APA guidelines adhered to purpose of the study except when withholding information or providing misinformation is essential to the investigation	consent of parents of child or those *in loco parentis* is prerequisite to obtaining consent of child child has right to refuse to participate